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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,071	05/26/2006	Brian Smith	20750-0043U1 066.US2.PCT	1893
26204	7590	05/21/2009	EXAMINER	
FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			05/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/561,071	Applicant(s) SMITH ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,9,10,14,16,17,21,26,30,31,35,40,44,45,49,54,58,59,63,68,72-78,81,82,84,90,91,93,94,96,97,99,104,124 and 126-131.

Continuation of Disposition of Claims: Claims rejected are 1-3,9,10,14,16,17,21,26,30,31,35,40,44,45,49,54,58,59,63,68,72-78,81,82,84,90,91,93,94,96,97,99,104,124 and 126-131.

DETAILED ACTION

Claims 1-3, 9, 10, 14, 16, 17, 21, 26, 30, 31, 35, 40, 44, 45, 49, 54, 58, 59, 63, 68, 72-78, 81, 82, 84, 90, 91, 93, 94, 96, 97, 99, 104, 124 and 126-131 are pending in the application.

This action is in response to applicants' amendment dated March 2, 2009. Claims 1-3, 9, 10, 14, 16, 17, 21, 26, 30, 31, 35, 40, 44, 45, 49, 54, 58, 59, 63, 68, 72-78, 81, 82, 90, 91, 94, 97, 104 and 124 have been amended, claims 79, 80 and 125 have been canceled and claims 126-131 are newly added.

Response to Arguments

Applicant's arguments filed March 2, 2009 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-3, 9, 10, 14, 16, 17, 21, 26, 30, 31, 35, 40, 44, 45, 49, 54, 58, 59, 63, 68, 72-82, 84, 90, 91, 93, 94, 96, 97, 99, 104, 124 and 125 of the last office action labeled paragraph 1, the applicants' the applicants' arguments have been fully considered, however they were not found persuasive.

The claims, insofar as they embrace hydrates and solvates are not enabled. The numerous examples presented all failed to produce a hydrate or a solvate. The evidence of the specification is thus clear: These compounds do not possess the property of forming hydrates or solvates; there is no evidence that such compounds even exist. Thus, this is a circumstance where the "specification is evidence of its own inadequacy" (*In re Rainer*, 377 F.2d 1006, 1012, 153 USPQ 802, 807). These cannot

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be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here: there is no evidence that hydrates or solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that hydrates or solvates can be made, or limit the claims accordingly.

Claims 1-3, 9, 10, 14, 16, 17, 21, 26, 30, 31, 35, 40, 44, 45, 49, 54, 58, 59, 63, 68, 72-78, 81, 82, 84, 90, 91, 93, 94, 96, 97, 99, 104, 124 and 126-131 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2 in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that the one of ordinary skill in the art would accept that 5-HT_{2C} agonists can decrease food intake and induce satiety, can treat the disorders recited by amended claim 81, etc. The applicants' also stated that one of skill in the art would be able to identify those who

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have the potential of becoming afflicted with the disorders recited by newly added claim 126. It is not known which behavioral disorders associated with dementia or age-related conditions and aggressivity the applicants refer. Frankle provided herewith indicates that aggressivity **may** benefit from modulation of the 5HT_{2C} receptor of which is speculative. Binetti et al., provided herewith indicates that the behavioral changes associated with Alzheimer's Disease includes apathy, agitation, delusions, depressive symptoms, anxiety, irritability, and disturbances of sleep and appetite. Tohda et al., also provided herewith indicates that the behaviors associated with depression include over-eating, hyperexcitability, and epileptic convulsions.

Furthermore, recent article by Lacivita et al., (2006) states that several lines of evidence suggest a role of 5-HT_{2C} receptor in appetite regulation. Additionally, it is stated that 5-HT_{2C} receptors could also be a target for the treatment of depression. Selective 5-HT_{2C} receptor agonists have demonstrated *in vivo* activity in animal models **suggestive** of therapeutic action against depression, obsessive-compulsive disorder, and panic disorders. The speculative nature of 5-HT_{2C} receptor agonists after the filing of this application for patent does not set forth an enabling disclosure for the treatment let alone the prophylaxis of the diseases and disorders claimed herein.

Additionally, the great diversity of diseases falling within the "cardiovascular disorders" category means that it is contrary to medical understanding that any agent, let alone the genus of formula I could be generally effective against such disorders. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

As stated in the last office action while being enabling for the treatment of obesity, does not reasonably provide enablement for the treatment and prophylaxis of depression, anxiety disorders, psychoses, schizophrenia and cardiovascular disorders, or the prophylaxis of obesity.

Claims 78 and 126-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3 in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that the methods of treating drug and alcohol addiction. However, as stated in the last office action the notion that a compound could be effective against drug and alcohol addiction in general is contrary to our current understanding of how chemical dependencies operate. There is not, and probably never will be, a pharmacological treatment for "drug addiction" generally. That is because "drug addiction" is not a single disease or cluster of related disorders, but in fact, a collection with relatively little in common. Addiction to barbiturates, alcohol, cocaine, opiates, amphetamines, benzodiazepines, nicotine, etc all involve different parts of the CNS system; different receptors in the body. For example, cocaine binds at the dopamine re-uptake site. Heroin addiction, for example, arises from binding at the opiate receptors, cigarette addiction from some interaction at

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the nicotinic acid receptors, many tranquilizers involve the benzodiazepine receptor, alcohol involves yet another system, etc. All attempts to find a pharmaceutical to treat chemical addictions generally have thus failed.

While recent article by Muller et al., (2006) indicates that 5-HT_{2C}-receptor agonist Ro600175, suppresses the Δ 9-tetrahydrocannabinol (the active ingredient of marijuana) induced increase in DA cell firing in the VTA. Muller is speculative as to the use of 5-HT_{2C} agonist in the treatment of other addictive drug classes.

Additionally, recent article by Lacivita et al., (2006) suggests that Ro 600175 reduces responding for intravenous cocaine and nicotine, and oral ethanol consumption and suggests a potential for selective 5-HT_{2C} receptor agonists in the treatment of various substance abuse disorders.

Claims 78, 81 and 131 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention, for reasons of record and stated above.

4. With regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 4 in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that claim 78 is directed to a method of agonizing the 5-HT_{2C} receptor. However, a method for agonizing 5-HT_{2C} activity in a cell does not set forth the metes and bounds of the claim. The rejection of claim 78 is on the grounds that it is indefinite in that it is not known

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which diseases are capable of being responsive to an agonist of the 5-HT_{2C} receptor.

The scope of diseases and/or disorders associated with the activity of the 5-HT_{2C} receptor could alter over time. The applicants' are not entitled to preempt the efforts of others. Thus the applicants have not set forth the metes and bounds of the claim.

Claim 78 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated March 2, 2009, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a. Claim 9 is vague and indefinite in that it is not known what is meant by "The compound according claim 1".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624